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BEFORE THE DEPARTMENTAL APPEALS BOARD  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:	*	FOOD AND DRUG ADMINISTRATION
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KORANGY RADIOLOGY ASSOCIATES, P.A., t/a BALTIMORE IMAGING CENTERS,	*	ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY
	*	
And	*	FDA Docket: 2003H-0432
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AMILE A. KORANGY, M.D.	*	
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RESPONDENTS' NOTICE OF APPEAL AND REQUEST FOR ORAL ARGUMENT

Respondents, by their undersigned attorneys, hereby file a Notice of Appeal, pursuant to 21 CFR 17.47, in the above-captioned case, appealing Administrative Law Judge's Partial Summary Decision, issued May 27, 2004, and Initial Decision, issued December 17, 2004 (copies enclosed herewith). Oral argument before the Board is hereby requested.

The following specific Exceptions are herein raised by way of appeal:

A.     Partial Summary Decision.

1.     The "Discussion of Law," (page 8), and the "Conclusions and Order," (page 10), both conclude that each Respondent is liable for 192 violations of 42 USC §263b(h)(3)(D). Respondents believe that, having determined that each Respondent was liable for one violation of 42 USC §263b(h)(3)(A), the Administrative Law Judge ("ALJ") was precluded from finding violations of §263b(h)(3)(D) based upon the same factual allegations.

B.     Initial Decision.

1.     The ALJ denied Respondents' argument to the effect that the proposed Civil Money Penalties ("CMPs") were issued illegally because of a lack of compliance with the provisions of 42 USC §263b(h)(4), which require that the Secretary develop and implement procedures with respect to when and how each of the sanctions contained in the Mammography Act will be imposed. (Pages 2 and 3).

Additionally, the ALJ did not address Respondents' position that the manner in which notice was intended to be provided to Respondents also failed to meet statutory requirements.

2. The ALJ denied Respondents' argument to the effect that the FDA (referred to as "the Center" in the applicable regulations) did not meet its burden of proof to establish the appropriateness of the CMPs sought in this case. (Page 3). The regulations, at 21 CFR 17.33, place that burden of proof on the Center.

3. The ALJ fashioned an alternative sanction (penalties reduced from those initially imposed). (Pages 8 and 9). This was done through the rejection of Respondents' argument that the ALJ had no power to revise the proposed sanctions, given the Center's failure to (a) meet the burden of proof requirements of 21 CFR 17.33, and (b) produce the procedures required by 42 USC §263b(h)(4). (Page 3). Further, the recommended modification of the CMP is arbitrary and capricious, as no rationale is presented by the ALJ to justify its adoption.

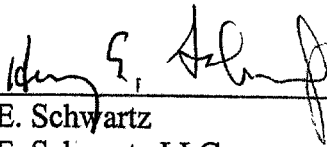
4. The ALJ rejected, without any consideration, Respondents' arguments that, to be rational (and not arbitrary and capricious), the penalties sought must be proportional to penalties sought in extremely similar cases. (Page 4).

5. The ALJ determined that Respondents have the ability to pay the CMPs sought by the FDA in the instant case through the acceptance of inappropriate evidence over the Motion to Strike of the Respondents. (Page 5 through 8). The ALJ called for simultaneous post-hearing briefs, denied Respondents' attempt to answer allegations made in the Center's brief, and refused to strike voluminous documentary "evidence" accompanying the Center's post-hearing brief. The ALJ would not accept a two-page response because reading it appeared to be too much of a burden, yet the ALJ refused to strike evidence that was not presented before or during the hearing, and pertaining to which the ALJ refused to allow any discussion or cross-examination. Then the ALJ spent half of his Initial Decision discussing this "evidence" that was accepted without any opportunity for response whatsoever by Respondents. This was an egregious violation of due process, particularly in light of the fact that the ALJ totally ignored IRS filings of both Respondents, as well as a statement of financial condition of both Respondents provided by an independent certified public accountant. All of these documents were admitted into the record, but ignored by the ALJ.

For the foregoing reasons, amplified in the accompanying Brief of Respondents, Respondents request that the Board reverse the findings of the ALJ in this case, and determine and order that the CMPs issued by the FDA be stricken.

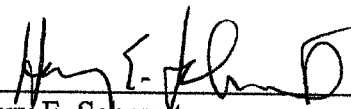
In the alternative, Respondents request that the Board reverse and strike the CMP findings with respect to the 192 violations of 42 CFR 263b(h)(3)(D) for each Respondent.

Respectfully Submitted;

  
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Henry E. Schwartz  
Henry E. Schwartz LLC  
901 Dulaney Valley Road, Suite 400  
Towson, MD 21204  
410. 938.8703  
[henryeschwartzllc@verizon.net](mailto:henryeschwartzllc@verizon.net)

**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on this 13<sup>th</sup> day of January, 2005, a copy of the foregoing Respondents' Request for Protective Order was mailed, postage prepaid, to Marci Norton, Esquire, and Jennifer Dayok, Esquire, Office of the General Counsel, Food and Drug Administration, 5600 Fishers Lane, GCF-1, Rockville, MD 20857.

  
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Henry E. Schwartz